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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,221	08/10/2001	Joel R. Haynes	DE-3-C2-PUS	3163

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INTELLECTUAL PROPERTY DEPT.
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EXAMINER
FOLEY, SHANON A

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 01/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/830,221	Applicant(s) HAYNES ET AL.	
	Examiner Shanon Foley	Art Unit 1648	

-- Th MAILING DATE of this communication appears on the cov r sh et with the correspondence addr ss --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18 and 20-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18 and 20-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Notice to Comply* .

DETAILED ACTION

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. (See page 17 of the disclosure for example.) Applicant is requested to return a copy of the attached Notice to Comply with the response.

Claim Objections

Claim 16 is objected to because of the following informalities: the claim lists "bobcats and lynx" twice in the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-18 and 20-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCluskie et al. (Antisense and Nucleic Acid Drug Development. 1998; 8: 401-414) and Paoletti (US 5,505,941).

Claims 1-2 are drawn to delivering a nucleic acid and a method of eliciting an immune response (claim 5) to an antigen in a felid (claims 15-17) by administering (claim 20) a nucleic

acid encoding an antigen (claims 4 and 6) complexed with a cationic lipid. The specific cationic lipid is tetramethyltetraalkyl spermine analog lipid (claim 13). The composition elicits an antibody (claim 7) and a cell-mediated response (claim 8) and protects the felid against disease (claim 9) and results in 75-100% seroconversion rate (claims 21 and 22). The composition is administered in a single administration (claim 18) and also comprises an immunomodulator (claim 14) or an excipient (claim 27). The antigen is any feline disease antigen, but is more specifically a rabies glycoprotein G (claims 10-12). The nucleic acid : lipid concentration ranges between 1:10 and 10:1 (claim 23) with the nucleic acid present in a dose of not more than 75 micrograms (claim 25) or ranges from 75-1000 micrograms (claim 24) and is dehydrated and rehydrated prior to administration (claim 26). Claim 3 is drawn to a method of protecting a felid from rabies infection by administering a nucleic acid encoding rabies glycoprotein G complexed to a cationic lipid.

Paoletti teaches a method of inducing an immune response in cats with a recombinant avipox virus by administering a composition comprising a DNA encoding antigens from various pathogens, including rabies glycoprotein G in a vaccine composition. The administration is accomplished by multiple routes of inoculation and is present with a suitable carrier. Paoletti also teaches that the recombinant induces seroconverting antibody response after a single administration of the vaccine composition, see claims 1, 3-12, 18, 31, 32, column 15, lines 26-44 and Table VI, and column 35, lines 30-50 and Table XIV.

Paoletti does not teach complexing the nucleic acid with a cationic lipid or more specifically, tetramethyltetraalkyl spermine analog lipid, incorporating an immunomodulator,

inducing a cell-mediated response, the instant dose ranges of the DNA, or the nucleic acid to lipid ratio.

However, McCluskie et al. teach conventional therapeutic immunomodulators that induce specific cell-mediated responses, see the introduction section on pages 401-402. McCluskie et al. also teach complexing plasmid DNA with tetramethyltetraalkyl spermine analog lipid within the range of the instant DNA:lipid ratio claimed and administering up to 100 micrograms of plasmid DNA, see "Cationic and neutral lipids" , "Preparation of liposomes" and "Preparation of plasmid-liposome DNA complexes" on pages 402-403.

One of ordinary skill in the art at the time the invention was made would have been motivated to incorporate the recombinant virus of Paoletti et al. with the cationic lipid of McCluskie et al. to obtain better transfection efficiencies, increase retention times and reduce the rate of degradation, see the first full paragraph of page 409 and the paragraph bridging pages 409-410 of McCluskie et al. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation for combining the recombinant vector of Paoletti with the cationic lipid formulation of McCluskie et al. because Paoletti teaches that the recombinant avipoxvirus is safer than other live or killed virus vaccines and expresses an antigenic determinate, but does not replicate in a mammalian host and McCluskie et al. stresses using vectors that reduce inadvertent infection, see the introduction section.

Although neither reference teaches dehydrating and rehydrating the formulation, lyophilized vaccine formulations are conventionally used in the vaccine art. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art, absent unexpected results to the contrary.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley
December 24, 2002

JAMES HOUSEL 12/30/02
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Application No.: 09830221

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- [ ] 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- [X] 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- [ ] 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- [ ] 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- [ ] 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- [ ] 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- [ ] 7. Other:_____

Applicant Must Provide:

- [ ] An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- [X] An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- [X] A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:
For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
PatentIn Software Program Support (SIRA)
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